UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

[UNDER SEAL],	**Case No.** 2:18 cv - 195
Plaintiff,	**COMPLAINT**
v.	
[UNDER SEAL],	**FILED IN CAMERA AND UNDER SEAI PURSUANT TO 31 U.S.C. §3730(b)(2)**
Defendant.	

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(DO NOT PLACE ON PACER)

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF VERMONT

UNITED STATES OF AMERICA, ex rel. TOBY MARKOWITZ AND ELIZABETH RINGOLD, **Plaintiffs,** **vs.** **NEXTGEN HEALTHCARE, INC. AND MEDICALISTICS, LLC,** **Defendants.**	**Case No.** **COMPLAINT FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT** **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)** **JURY TRIAL DEMANDED**

Plaintiff-Relators Toby Markowitz and Elizabeth Ringold, through their attorneys, on behalf of the United States of America (the "Government" or the "Federal Government"), for their Complaint against defendants NextGen Healthcare, Inc. and Medicalistics, LLC (collectively, "Defendants"), allege based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent records, statements and claims made and caused to be made by Defendants and/or their agents and employees, in violation of the federal False Claims Act, 31 U.S.C. §§ 3729 et seq. ("the FCA").

2. This action alleges that Defendants caused the United States to spend millions of dollars in false claims for payment for NextGen's electronic health record software including millions of dollars in false claims to be submitted to the Department of Health and Human Services (HHS) for federal incentive payments through the Electronic Health Record (EHR)

Incentive Programs and related programs.

3. Pursuant to the Health Information Technology for Economic and Clinical Health Act (HITECH Act), HHS established the Medicare and Medicaid EHR Incentive Programs (also known as the "Meaningful Use program"), which provided incentive payments to healthcare providers who demonstrated "meaningful use" of certified EHR technology. At the same time, many public entities, including Community Health Centers (CHCs) and Federal Qualified Health Centers (FQHCs); federal, state and local correctional facilities; Indian Health Services facilities; and Patient-Centered Medical Homes, made direct purchases of certified EHR technology for clinical practice.

4. Defendant NextGen Healthcare, Inc. ("NextGen") developed and sold EHR software to healthcare providers throughout the United States, including in this judicial district. Defendant Medicalistics, LLC ("Medicalistics") provided NextGen with EHR consulting and project management services, and also provided NextGen with an electronic medication administration software application incorporated into NextGen's EHR system.

5. This Complaint alleges that NextGen's EHR system suffers from pervasive flaws that make it incapable of meeting a variety of Meaningful Use objectives and measures in operation and that make it incapable of meeting direct purchase requirements of public entities. These flaws prevent healthcare providers that use NextGen's EHR system from providing clinical care safely and reliably. Many of the flaws create an acute risk to patient health and safety. In addition, problems with implementation of NextGen's software compound the problems with the software itself, making the NextGen system even more unreliable and often dangerous.

6. Defendant Medicalistics aided and abetted NextGen's misconduct by providing a

flawed medication administration record product for use in NextGen's EHR system.

7. Based on the inability of NextGen's software to meet Meaningful Use objectives and measures in operation, and based on information and belief after a reasonable investigation, Relators allege that NextGen knowingly and falsely attested to its certifying body that its software complied with the requirements for certification and for the payment of incentives under the Meaningful Use program. NextGen's EHR system would not have been eligible for certification if the certifying body had known that NextGen could not perform many of the critical functions it falsely represented it could perform.

8. Medical providers using NextGen's EHR system could not meet the requirements for demonstrating Meaningful Use of certified EHR technology and should have been ineligible for MU incentive payments. As a result of the use of NextGen's EHR system, these providers presented or caused to be presented false attestations to the Government that their EHR system complied with required Meaningful Use objectives and measures to obtain Meaningful Use subsidies.

9. The Government would not have made Meaningful Use subsidy payments to the providers that used NextGen's software if it had known of the flaws with the software and problems with implementation of the software that resulted in knowing failure to perform required functions.

10. In addition, Defendants fraudulently induced public entities to purchase Defendants' EHR products by concealing the flaws discussed in this Complaint.

11. This Complaint also alleges that NextGen provided remuneration to decision-makers to influence their decision to purchase NextGen's EHR products, in violation of the Anti-Kickback Statute. Requests to the Federal Government for payments that are a

consequence of unlawful kickbacks constitute false claims.

12. Defendants' false and fraudulent statements and conduct alleged in this Complaint violate the federal False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq.* The FCA allows any person having information about an FCA violation (referred to as a *qui tam* plaintiff or "relator") to bring an action on behalf of the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

13. *Qui tam* plaintiffs Toby Markowitz and Elizabeth Ringold seek through this action to recover all available damages, civil penalties, and other relief for the FCA violations alleged herein in every jurisdiction to which Defendants misconduct has extended.

II. PARTIES

14. Plaintiff United States of America is the real party in interest herein. The United States, acting through HHS, administers the Medicare program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 (Medicare), and administers grants to states for Medical Assistance Programs pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396, *et seq.* (Medicaid). The United States, acting through HHS, also administers the Meaningful Use program and a certification program for EHR technology. The United States also has directly purchased or subsidized the NextGen electronic health record program for the Indian Health Services; Community Health Centers (CHCs) and Federal Qualified Health Centers (FQHCs); correctional facilities; and other recipients of federal funding.

15. *Qui tam* plaintiff/relator Toby Markowitz is a resident of Moncks Corner, South

Carolina. He has been a Registered Nurse since 2001 and worked continuously as an RN since then. He has held positions as Charge Nurse and Case Manager in Home Health, Long Term Care, Mental Health, Hospice, Juvenile Justice System, and currently in Adult Corrections. He started working at the Lieber Correctional Institution within the South Carolina Department of Corrections ("SCDC") in 2009 and is currently employed there. Mr. Markowitz brings this action on behalf of the United States of America, the real party in interest.

16. *Qui tam* plaintiff/relator Elizabeth Ringold is a resident of Summerville, South Carolina. She has been a licensed Nurse Practitioner ("NP") since 2008 and worked in that capacity first in private practice and then in the public sector. She has worked as an NP for SCDC since August 2011. Relator Ringold brings this action on behalf of the United States of America, the real party in interest.

17. Defendant NextGen Healthcare, Inc. is a California corporation with headquarters in Irvine, California. The company changed its name from Quality Systems, Inc. to its present name on September 6, 2018. NextGen sells EHR and practice management systems in the ambulatory care and specialty care markets. NextGen sells its EHR products throughout the United States, including in this judicial district. According to its most recent annual report, NextGen had total revenues in excess of $530 million in fiscal year 2018 (ending March 31, 2018). NextGen's securities are listed on the NASDAQ Global Select Market under the symbol "NXGN." The company's website is www.nextgen.com.

18. Defendant Medicalistics, LLC is a privately-owned company organized under the laws of Kansas with offices located in Leawood, Kansas and Dallas, Texas. Medicalistics is engaged in the business of providing project management and consulting services for EHR systems throughout the United States. It is an authorized vendor of NextGen's EHR system.

One of Medicalistics' products is "eZmar," an electronic medication administration record software designed to help correctional facilities administer electronic medication records.

III. JURISDICTION AND VENUE

19. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Although the issue is no longer jurisdictional after the 2009 amendments to the FCA, to Relators' knowledge there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint, as those concepts are used in 31 U.S.C. § 3730(e), as amended by Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901-02.

20. Moreover, whether or not such a disclosure has occurred, Relators would qualify as "original sources" of the information on which the allegations or transactions in this Complaint are based. Before filing this action, Relators voluntarily disclosed to the Government the information on which the allegations or transactions in this Complaint are based. Additionally, Relators have direct and independent knowledge about the misconduct alleged herein and that knowledge is independent of and materially adds to any publicly disclosed allegations or transactions relevant to their claims. Furthermore, this action is not based primarily on any public disclosure that would merit limiting an award to Relators to no more than 10 percent of the proceeds of the action, under 31 U.S.C. § 3730(d)(1).

21. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendants have minimum contacts with the United States. Moreover, one or more of the Defendants can be found in and/or transact business in the District of Vermont.

22. Venue is proper in the District of Vermont pursuant to 28 U.S.C. §§ 1391(b)-(c) and 31 U.S.C. § 3732(a) because one or more of the Defendants can be found in and/or transact business in this District, and/or because violations of 31 U.S.C. §§ 3729 *et seq.* alleged herein occurred within this District. At all times relevant to this Complaint, one or more of the Defendants conducted business within this District.

IV. STATUTORY AND REGULATORY BACKGROUND

A. The False Claims Act

23. The FCA imposes civil liability on any person who, *inter alia:* (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government a false or fraudulent claim for payment or approval; (2) knowingly makes, uses or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government; or (4) conspires to violate the FCA. 31 U.S.C. §§ 3729(a)(l)(A), (B). (C), and (G).

24. The FCA defines a "claim" to include "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property that - (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest ...." *Id.* at § 3729(b)(2).

25. The FCA defines the terms "knowing" and "knowingly" to mean "that a person, with respect to information - (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard

of the truth or falsity of the information. *Id.* at § 3729(b)(1)(A). The FCA does not require proof of specific intent to defraud. *Id.* at § 3729(b)(1)(B).

26. The FCA provides that the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* at § 3729(b)(4).

27. Any person who violates the FCA is liable for a mandatory civil penalty for each such claim, plus three times the damages sustained by the Government. *Id.* at § 3729(a)(1).

B. The Anti-Kickback Statute

28. The federal Anti-Kickback Statute (AKS), 42 U.S.C. § 1320a-7b(b), provides, in pertinent part:

> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -
>
> > (A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> > (B) To purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

29. Accordingly, manufacturers of products paid for in whole or in part by federal healthcare programs may not offer or pay any remuneration, in cash or in kind, directly or indirectly, to induce physicians, medical practices, or others to order or recommend products paid for in whole or in part by Federal healthcare programs such as Medicare and Medicaid.

30. The Patient Protection and Affordable Care Act (PPACA), Publ. L No. 111-48,

124 Stat. 119 (2010), provides that violations of the AKS are *per se* violations of the FCA: "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for the purposes of [the False Claims Act]."

31. The PPACA also clarified the intent requirement of the Anti-Kickback Statute, and provides that "a person need not have actual knowledge of this section or specific intent to commit a violation" of the AKS in order to be found guilty of a "willful violation." *Id.*

C. Certified EHR Technology and the Meaningful Use Program

31. On February 17, 2009, the HITECH Act was enacted to promote the adoption and meaningful use of certified EHR technology. Under the HITECH Act, the HHS Office of the National Coordinator for Health Information Technology (ONC) established a certification program for EHR technology. As part of the certification program, EHR vendors attest to ONC authorized certification bodies (ACB) and accredited testing laboratories (ATL) that their software meets the certification requirements established by ONC. The certification bodies and testing laboratories test and certify that vendors' EHRs are compliant with the certification requirements.

32. Through the Meaningful Use program, CMS makes incentive payments to healthcare providers for demonstrating meaningful use of certified EHR technology. Individual practitioners (Eligible Professionals) could qualify for up to $43,720 over five years from Medicare (ending after 2016) and up to $63,750 over six years from Medicaid (ending after 2021).

33. In order to qualify for incentive payments under the Meaningful Use program, Eligible Professionals are required, among other things, to: (1) use an EHR system

that qualified as certified EHR technology; and (2) satisfy certain objectives and measures relating to their meaningful use of the certified EHR technology.

34. HHS implemented the certification criteria and incentive payment requirements in multiple stages. On January 13, 2010, HHS published in the Federal Register interim final rules setting forth the "2011 Edition" certification criteria and a proposed rule setting forth the "Stage 1" requirements for incentive payments. HHS finalized these rulemakings by publication in the Federal Register on July 28, 2010. In Stage 1, an Eligible Professional's use of certified EHR technology generally needed to satisfy fifteen "core objectives" and five out of ten "menu set objectives."

35. On September 4, 2012, HHS published in the Federal Register the final rules setting forth the "2014 Edition" certification criteria and "Stage 2" requirements for incentive payments. In Stage 2, an Eligible Professional's use of certified EHR technology generally needed to satisfy seventeen "core objectives" and three out of six "menu set objectives."

36. On October 16, 2015, CMS published in the Federal Register a final rule with comment period setting forth the "Modified Stage 2" requirements for incentive payments. For years 2015 through 2017, Modified Stage 2 eliminated the concept of "menu set objectives" and required all Eligible Professionals to attest to a single set of objectives and measures.

37. In October 2015, CMS also released a final rule that established Stage 3 in 2017 and beyond, which focuses on using certified EHR technology to improve quality, safety and efficacy of health care, including promoting patient access to self-management tools and improving population health.

38. Starting in 2015, all providers were required to use technology certified to the

2014 Edition. For 2016 and 2017, providers could choose to use technology certified to the 2014 Edition or the 2015 Edition.

39. To qualify for incentive payments in each Stage of the Meaningful Use program, healthcare providers are required each year to attest that they used certified EHR technology and satisfied the applicable Meaningful Use objectives and measures. Use of certified EHR technology and satisfaction of applicable Meaningful Use objectives and measures are material to payment under the Meaningful Use program.

40. To obtain certification, EHR vendors must attest to an ACB that their EHR product satisfies the applicable certification criteria, submit to certification testing by an ATL, and pass such testing.

41. Certification testing is based on the certification criteria the vendor represents its software satisfies and on which it requests to be tested and certified. The certification and testing bodies use standardized testing protocols ("test scripts"), which identify each step the vendor will be required to take during testing. The test scripts are available to vendors in advance of their testing date. These scripts are intended to test representative aspects of the criteria under examination and are not intended to test all aspects of the criteria. The certification body relies on the accuracy and good faith of the vendor's attestations to the certification body with regard to aspects of the criteria that are not directly tested.

42. After obtaining certification, an EHR vendor must maintain that certification by complying with all applicable conditions and requirements of the certification program. Among other things, the EHR product must be able to accurately, reliably, and safely perform its certified capabilities while in use in healthcare providers' offices. EHR vendors must

cooperate with the processes established by ONC for testing, certifying, and conducting ongoing surveillance and review of certified EHR technology.

43. The CMS rules governing the Meaningful Use program recognize that healthcare providers rely on certification for assurance that an EHR product meets the applicable certification criteria, including that it possesses the certified capabilities that healthcare providers will need to use to achieve relevant objectives and measures, and that the software will perform in accordance with applicable certified capabilities.

44. Starting in 2017, the Medicare EHR Incentive Program was incorporated into the Merit-based Incentive Payment System (MIPS) under the Quality Payment Program created by the Medicare Access and CHIP Reauthorization Act (MACRA), 42 U.S.C. 1395ee. MIPS is discussed further in ¶¶ 50-53 below.

D. Certified EHR Technology and the PQRS Program

45. The Physician Quality Reporting System (PQRS) is a voluntary reporting program that provides a financial incentive for health care professionals who participate in Medicare to submit data to CMS on specified quality measures for covered Physician Fee Schedule services furnished to Medicare Part B Fee-for-Service beneficiaries.

46. For reporting years 2012 through 2014, CMS provided physicians who satisfactorily reported data on the required quality measures an incentive payment of 0.5% of their total allowed charges for the reporting year. Starting in 2015, the program applied a negative payment adjustment to practices with Eligible Professionals that do *not* satisfactorily report data on quality measures. The penalty was 1.5% for 2015 and increased to 2.0% for 2016 and subsequent years. Those who report satisfactorily for the 2016 program year avoid the 2018 PQRS negative payment adjustment.

47. Providers can participate in PQRS either with or without an EHR. Those who have an EHR can report PQRS data directly through their EHR.

48. The measures for PQRS are divided into two groups: Individual Measures and Measures Groups. An eligible professional may choose to report any combination of Individual Measures or choose a specific Measures Group. Measures Groups include a minimum of 6 individual measures and normally a maximum of 11 measures. The individual measures in the Measures Groups all relate to a specific diagnosis or problem such as diabetes, coronary heart disease, or others. Also, beginning in 2016, Eligible Professionals must include one cross-cutting measure.

49. The last program year for PQRS was 2016. Starting in the 2017 program year, PQRS became part of the Merit-based Incentive Payment System (MIPS) under the Quality Payment Program. See ¶¶ 50-53 below.

E. The Merit-Based Incentive Payment System ("MIPS")

50. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) created the Quality Payment Program to replace three programs that ended with the 2016 reporting period: the Medicare EHR Incentive Program; the PQRS program; and the Value-Based Modifier program.

51. The Quality Payment Program has two tracks: the Merit-based Incentive Payment System (MIPS) and the Advanced Alternative Payment Models (APMs).

52. MIPS payment adjustments are applied to Medicare Part B payments two years after the performance year, with 2019 being the payment adjustment year for the 2017 performance year.

53. Although as of the date of preparation of this Complaint, MIPS payment

adjustments have not yet been made under the Quality Payment Program, Relators allege based on information and belief that the practices described herein that cause false claims to be submitted to the Government under the Meaningful Use program will cause false claims to be submitted to the Government under the Quality Payment Program.

F. The 21st Century Cures Act

54. The 21st Century Cures Act, enacted into law in 2016, requires EHR products to perform certain functions reliably in real-world environments to maintain certification. These requirements address interoperability, information sharing, usability, security and privacy.

55. Electronic health records programs that do not meet these functional standards may be identified through routine or reactive surveillance by the ONC authorized certification bodies (ACB) and accredited testing laboratories (ATL) for decertification.

56. To receive continued payment under the Medicare value-based payment programs, providers must use certified EHR products.

G. Direct Federal Purchases of Certified EHR Products

57. The Federal Government funds direct purchases of certified EHR products by several public entities responsible for providing healthcare, including but not limited to the following:

58. Indian Health Service. The Indian Health Service (IHS), an agency within the Department of Health and Human Services, is responsible for funding health services to American Indians and Alaska Natives. The IHS currently funds health services to approximately 1.5 million American Indians and Alaska Natives. On its website, NextGen states that its "Tribal Health" Specialty Division provides EHR products and services to "more than 45 tribal partners."

59. Federal Bureau of Prisons. The Bureau of Prisons, a division of the United States Department of Justice, manages the federal prison system and is responsible for the healthcare of the federal inmate population. Similarly, each State manages its state prison system and is responsible for the healthcare of its state inmate population. On its website, NextGen states that its "Correctional Health" Specialty Division provides EHR products and services to correctional institutions throughout the United States.

60. Community Health Centers ("CHS") and Federally Qualified Health Centers ("FQHC"). These health centers, which provide healthcare to medically underserved and uninsured communities, receive federal funding under Section 330 of the Public Health Service Act. On its website, NextGen states that its "CHC/FQHC" Specialty Division provides EHR products and services to "one in three" Community Health Centers and Federally Qualified Health Centers throughout the United States.

61. Patient-Centered Medical Homes (PCMH). PCMH is a team-based model of care that begins with the primary care provider and coordinates care across multiple specialties to improve and maximize health outcomes. The Federal Government encourages PCMHs to adopt EHR technology and offers incentive payments to the PCMHs.

V. ALLEGATIONS

A. Background

1. NextGen's EHR Products

62. NextGen sells two EHR products: the "Enterprise EHR" and the "Office EHR." NextGen's "Enterprise EHR," formerly known as NextGen's "Ambulatory EHR," is built for large medical practices and the server is housed on the premises of the client. NextGen's "Office EHR" (formerly "MediTouch") is a cloud-based system, designed primarily for independent

practices and billing services. The primary difference between the two products is that the former uses an on-site server and the latter uses a cloud- based server. In this Complaint, the term "NextGen's EHR system" refers to both EHR products.

63. According to publicly available certification documents, NextGen's Ambulatory EHR, version 5.8.0.77, was certified as 2014 Edition compliant on February 19, 2014; version 5.8.1 was certified as 2014 Edition compliant on August 4, 2014; version 5.8.2 was certified as 2014 Edition compliant on June 3, 2015; and version 5.8.3 was certified as 2014 Edition compliant on October 14, 2016. NextGen's Enterprise EHR version 5.9 was certified as 2015 Edition compliant on November 27, 2017; version 5.9.1 was certified as 2015 Edition compliant on May 8, 2018; and version 5.9.2 was certified as 2015 Edition compliant on October 24, 2018. NextGen's MediTouch version 5.0 was certified as 2015 Edition compliant on February 20, 2018.

64. Certification testing does not confirm that each criteria and standard is satisfied in full and under every conceivable scenario. Rather, testing takes a snapshot of a product's capabilities by ensuring it can pass certain pre-disclosed test cases.

65. As a predicate to obtaining certification for the various versions of its software, NextGen submitted an attestation form or forms to the testing authority representing that NextGen's EHR software satisfied the applicable certification criteria and that its software was capable of performing those criteria and standards in the field.

66. Upon information and belief based on the inability of NextGen's EHR system in operation at SCDC to meet MU requirements, Relators allege that NextGen misled the certification authority, either through misrepresentations in NextGen's attestations or through misconduct during the testing, to pass the certification testing and achieve certification for its

EHR system. Numerous examples of the software's failure to meet certification criteria are provided in ¶¶ 74-125 below.

67. As explained more fully below, Relators allege that:

(a) NextGen obtained 2014 Edition and 2015 Edition certification for the versions noted above without fully implementing all of the requirements for certification. NextGen did not ensure that the standards, implementation specifications, and criteria were truly met.

(b) NextGen's EHR software did not satisfy the Meaningful Use certification criteria and could not operate in the field in compliance with the requisite certification criteria.

(c) NextGen's EHR software does not satisfy the requirements for functionality set forth in the 21st Century Cures Act for continued certification.

2. Medicalistics' Products and Services

68. Medicalistics provides products and services to assist EHR vendors with management and implementation of their EHR systems in various settings. Medicalistics' services include EHR implementation, project management, training, and ongoing maintenance and support. Medicalistics has assisted NextGen in the implementation of its EHR system in various settings, including SCDC's prison facilities. Medicalistics also provides an electronic medication administration record system called "eZmar." NextGen incorporated eZmar into its EHR system at the SCDC prison facilities. eZmar is intended to help correctional facilities administer medication records, but, as detailed below, it failed miserably at this task at SCDC.

B. The Implementation of NextGen's EHR System in South Carolina's Prisons

69. In September 2016, the South Carolina Department of Corrections settled a class action lawsuit brought by prison inmates with disabilities. The settlement agreement required, among other provisions, that SCDC implement an electronic medical records system in South

Carolina's prisons, which house approximately 20,000 inmates in 21 prisons across the State. To fulfil this requirement, SCDC selected NextGen's EHR system for the State's prisons. SCDC implemented NextGen's EHR version 5.8.3.127.

70. Prior to implementing NextGen's EHR system, South Carolina's prisons used a mix of paper records and an electronic record system developed in the 1980s.

71. The transition to NextGen's EHR system in South Carolina's prisons took place in phases. In the first phase, in February 2017, a pilot rollout of the system was introduced into the State's two female prison facilities: the Camille Graham Correctional Institution in Columbia and the Leath Correctional Institution in Greenwood, South Carolina. In the second phase, beginning in May 2018, the EHR system was introduced into the State's six maximum security prisons: Broad River Correctional Institution in Columbia, Kirkland Correctional Institute in Columbia, Lee Correctional Institution in Bishopville, Lieber Correctional Institution in Ridgeville, McCormick Correctional Institution in McCormick, and Perry Correctional Institution in Pelzer, South Carolina. The system went "live" at Lieber Correctional Institution– where Relators work – on or about May 24, 2018. The State's remaining prison facilities implemented the system in the Summer of 2018.

72. The implementation and use of NextGen's EHR system in the South Carolina prisons has been disastrous for the providers and patients alike. Starting with the pilot program in the two women's facilities and continuing through implementation in the entire prison population, NextGen's EHR system, including eZmar, has been riddled with a multitude of serious problems. These problems extend to virtually every aspect of the system, including inaccurate and unreliable medical records, serious mistakes in medication tracking and administration, serious mistakes in e-prescribing, inadequate interface with laboratory and

diagnostic imaging services, inadequate security protections, inability to generate required medical reports, and deficient computerized provider order entry (CPOE) functionality, among many other issues.

73. Relators have discussed the problems regarding NextGen's EHR system with medical practitioners at several prisons in the State, and similar problems exist at all of these prisons. Virtually every practitioner in the South Carolina prison system with whom Relators have spoken regard NextGen's EHR system as woefully inadequate and worse than the antiquated system that SCDC used before it implemented NextGen's EHR system.

C. NextGen's EHR System Fails to Satisfy Required Certification Criteria

74. During the time period relevant to this complaint, NextGen knowingly released software that failed to satisfy required certification and Meaningful Use criteria.

75. Representative examples of the deficiencies in NextGen's EHR software related to certification and Meaningful Use criteria are provided below. NextGen was well aware of these deficiencies through complaints and concerns communicated by users, among other sources of information. Users at SCDC reported their complaints and concerns to SCDC's EHR Implementation Chief, who communicated them to NextGen.

1. NextGen's EHR System Fails To Reliably Document and Track Medications Administered to Patients

76. A significant defect in NextGen's EHR system is its inability to reliably document and track medications administered to patients. At the SCDC prisons, and in other settings in the United States, NextGen's EHR system incorporates Medicalistics' electronic medication administration software "eZmar" to help document and track medications.

77. Relators have encountered numerous flaws in the manner in which NextGen's EHR system documents and tracks medications provided to patients. Examples include:

78. Discontinued medications are often treated as active medications due to systemic flaws. When a medication is discontinued in NextGen's EHR, this information is typically not transmitted to the pharmacy nor reflected in the eZmar medication record. For example, if a prescriber discontinues one dosage of a medication and writes a new prescription for a different dosage, the system will fill both prescriptions unless the prescriber catches the error. The discontinued medication will appear under the "stopped" section on the medication list, but it remains active in the pharmacy system. Relator Ringold knows this because when she goes to discontinue one dosage of a medication and prescribe a different dosage, an alert comes on the screen and asks if she is certain that she wants to prescribe a duplicate medication. Providers have to call the pharmacy to manually remove a discontinued medication, and have to notify the nurses to remove it from the patient's next medication administration. This is a particularly dangerous flaw since the dosage of certain medications, such as Coumadin (a blood thinner), are changed frequently, and a duplicate dosage can be lethal. As another example, Relator Ringold prescribed one of her diabetic patients a diabetic medication in pill form. She later changed the dosage, which generated a second prescription. If she had not caught the duplicate prescriptions and canceled the superseded one, this could have had severe consequences of hypoglycemia if the patient had taken both pills at the same time.

79. Incorrect prescriber information in the medication record. Relator Ringold knows of 23 specific instances where prescriptions have shown up under her name as prescriber, even though she did not write the prescriptions. When the correct prescriber is not listed, he or she does not receive a missed dose notification or notification that a prescription needs to be renewed.

80. Frequent dosage errors in the medications in the active medication list.

Medication doses are frequently incorrect within the EHR system without known cause. For example, an epileptic patient that had been transferred to a different facility within the South Carolina prison system had been prescribed an anti-seizure medication twice a day (one tab in the morning and one tab at bedtime). The NextGen EHR, including the eZmar software, recorded the dosage as one tab in the morning only. After approximately one week of one tab in the morning (only), the patient had a seizure and fell off of his top bunk, hitting the concrete floor and injuring his head, neck and shoulder. (Epileptic drugs are monitored in the patient's blood. They must be within a therapeutic range for them to be effective. By the dosage being cut in half, the patient's blood level of the drug would have fallen to the sub-therapeutic range, thus resulting in him having the seizure.)

81. Frequent errors in the method or time of administration for medications in the active medications list. For example, on one occasion Haldol, a powerful anti-psychotic tranquilizer, was prescribed in tablet form, twice daily, but was changed by the EHR system to long-acting injection form twice daily. Since the long-acting injection form is normally given only *once every four weeks*, if this error had not been caught by an alert nurse and if the injection had indeed been given twice daily, it would have resulted in a dangerous and possibly fatal overdose.

82. Likewise, medications written as "prn" (meaning "as needed") have been changed to a prescribed dosage and frequency. In one recent example, an SCDC psychiatrist wrote the prescription for a psychiatric medication with a prescribed dosage and frequency, yet it showed up in eZmar and the EHR system as "prn." Relator Ringold investigated in order to try to find out whether the error had been caused by workflow or user error but could not identify any such problem and surmised that the problem arose from a software deficiency. Relator Ringold has

seen this happen particularly often with thyroid and HIV medications. Similarly, many prescriptions written by Relator Ringold with the instruction "KOP" (keep on person) have been transmitted to the pharmacy as "DXD" (administer dose by dose), and vice versa.

83. Medications in the EHR system also do not stay assigned to their designated administration time (e.g., morning only or evening only), which leads to administration at incorrect times. In the most extreme cases, the medications drop out of the medication administration record system altogether, with no explanation.

84. Frequent inconsistencies between the patient's "active medication list," the medication list in eZmar, and the medication list that the pharmacy has on file for the patient. These inconsistencies cause *extreme* confusion -- the nursing staff does not know which medication list is correct and which is mistaken – with a consequent risk of medication errors. On numerous occasions, the pharmacy has had record of a prescription but there is no record of it in NextGen's EHR system or in eZmar. Conversely, inmates will have active prescriptions listed in NextGen but none in eZmar or on file at the pharmacy. There have also been multiple instances of nurses documenting in their notes that medications were administered but this is not reflected in the patient's medication administration record. Relator Ringold also knows of at least two specific instances in which the EHR system generated hundreds of expired prescriptions to be filled by the pharmacy for administration to patients, but fortunately the pharmacist caught the error on both occasions and did not fill the prescriptions.

85. Problems with recording narcotics and controlled medications in NextGen and eZmar. Because of problems in the EHR system, staff at SCDC have to document narcotics and controlled medications on a paper sheet in the narcotics cabinet. This greatly reduces the utility of the EMR in a correctional setting.

86. The inability of NextGen's EHR system to reliably record medications creates a serious risk of over and under-dosing and failure to identify hazards associated with medications, including contraindications, quantity or dosage limits, and adverse drug interactions.

87. During October 2018, Relator Ringold performed an informal audit of medication errors at Lieber Correctional Institute and found medication errors in the electronic records of 71 out of 588 inmates in her audit. That is a medication error rate at 12.1% because of the EHR system, which means that over 1 in 10 patients was receiving the wrong medication, wrong dosage, or wrong method of administration. Such a high error rate is dangerous to patient health.

88. Due to the many flaws in the medication record in NextGen's EHR system, nurses have not been able to administer medication at regularly scheduled times as is expected at Lieber Correctional Institute. These regularly-scheduled times for administration of medication are called "pill passes" within institutional settings including correctional facilities. ("Pill pass" is also sometimes referred to as "pill call".) At the Lieber facility, one "pill pass" should involve approximately 350 patients.

89. At Lieber, there have been numerous incomplete pill passes because of flaws in the EHR system. There are often numerous patients inexplicably missing from the pill pass; or medications inexplicably missing from the patients' designated medications. To add to the confusion, pill passes often include medications for patients housed in other facilities (which raises the question of whether that patient is receiving his/her medication in the other facility).

90. Due to the flaws in NextGen's software, the EHR system is also unable to generate an accurate and complete "expiring medication report" that shows the prescriptions that will expire if not renewed. Relator Ringold has been told repeatedly that this functionality is "in

production" by Nextgen, but it is still not available. This is a significant deficiency that results in disruption in continuity of care. Because a provider has no ability to see what prescriptions are expiring, the prescriptions are not renewed until the patient brings it to their attention. By the time the prescription is renewed and arrives, the patient has been without his or her medication for a few days, which in many cases (e.g., diabetes medications, hypertension medications, etc.) is harmful to the patients.

91. As a tedious workaround for this problem, Relator Ringold has asked the SCDC pharmacy to email her an active prescription list from their legacy system (550+ pages), and Ms. Ringold manually reviews expiration dates for each prescription for each patient, renewing the prescription where appropriate.

92. One particular flaw in the medication administration record came to light following the suicide of an inmate in September 2018. In the EHR's active medication list, there is a "do not show" button for each medication listed. Based on instructions in the eZmar User Guide, medical staff understood that pushing the button would just remove a medication from a single pill call, i.e. single round of medication. Unbeknownst to the staff, however, pushing the button permanently removes the medication from the active list. In this particular incident, a depressed patient was prescribed an antidepressant. A nurse pushed the "do not show" button in order to remove the drug for one round of medication. Pushing the button, however, removed the medication from *all* of the following pill calls. This same patient was later transferred to another prison within the SCDC system. Weeks after arriving, this depressed patient was found hanging in his cell. During the investigation of his death, the problem concerning the "do not show" button came to light. Subsequent to this death, staff were warned not to touch the "do not show" button.

93. Another example of patient harm that can result from NextGen's flawed medication administration system involved a patient at one of SCDC's maximum security facilities in late October 2018. In this incident, the patient sought medical treatment for tremor/neurological complaints. It was later determined that he was suffering from lithium toxicity, but the nursing staff did not initially recognize this because there was no record that the patient had been given lithium in the NextGenEHR. The treating physician only caught the high lithium level because he received a paper lab report (of a blood test) over the fax machine, either the next day or day after that, at which time the inmate was sent to the ER for lithium toxicity. This was a close call that could have resulted in the inmate's death. It reflected two major flaws in the EHR system: inaccurate medication list (not showing the lithium dosage) and delay in reporting lab results (lack of lab interface is discussed further below).

2. The e-Prescribing Functionality of NextGen's EHR System is Flawed and Unreliable and Does Not Meet MU Requirements

94. Meaningful Use Stage 2 and Stage 3 criteria require healthcare providers to use certified EHR technology to generate and transmit prescriptions electronically (commonly referred to as e-prescribing). NextGen's EHR system uses Medicalistics' medication administration software eZmar to manage e-prescriptions. The e-prescribing functionality, like the medication administration and tracking functionality discussed above, is riddled with problems that render it non-compliant with certification and Meaningful Use criteria.

95. Examples of the persistent problems with the e-prescribing (aka "eRx") functionality include the following:

96. NextGen's e-prescriptions have a high rate of mistakes. The most common mistakes are different quantities or dosages in the eRx compared to the prescriber's order, and different frequency of administration or method of administration compared to the prescriber's

order. Even when the eRx is correct, the EHR system does not reliably transmit the eRx to the pharmacy. Relator Ringold has seen many instances in which the eRx was not received by the pharmacy. In these instances, there was no error alert; it looked like the eRx went through because the medication showed up on the patient's active medication list, but the eRx was never received by the pharmacy.

97. Prescriptions sent electronically often list the wrong medical professional as the prescribing provider. The consequence of this is that the correct prescribing provider cannot renew the prescription because a different, erroneous provider is listed as the prescriber. By the time it is straightened out, there is a disruption in continuity of care. An example was on September 26, 2018, when the staff sent Relator Ringold a Nexium renewal request for one of her patients, but a psychiatrist was mistakenly listed as the prescribing provider, which meant that Relator Ringold was unable to see the request for renewal. Eventually she had to manually go into the system and reorder the medication, but this type of error with the prescription can cause a serious/harmful disruption in continuity of care.

98. Multiple unexplained and unauthorized "sig" changes in the eRx. The abbreviation "sig" is written before the directions on a prescription. ("Sig" is an abbreviation for the Latin word "signetur," which means "let it be labeled.") An example of a sig change is a prescription written as 2x daily being sent to the pharmacy as 3x daily. For example, one typical example experienced by Relator Ringold involved Trazodone, a psychiatric medication for sleep. A staff psychiatrist wrote the patient's Trazodone prescription as once daily at bedtime; however, the EHR system generated an eRx for twice daily (1 in the morning and 1 at night). In another example, an eRx for anti-anxiety medication Buspar went from "1 po bid" (meaning one pill orally two times per day) on the eRx to "2 po tid" (meaning two pills orally three times per

day) on the Rx bottle received from the pharmacy.

99. eRx renewal results in duplicate prescriptions. When a provider discontinues one dosage of a medication and renews the eRx in a different dosage, NextGen's EHR system at the SCDC prisons duplicates the prescription at the pharmacy. If not caught, this flaw leads to overdoses. For a drug like blood thinner Coumadin that has frequent dosage changes, this flaw can cause a fatal medication error.

100. Non-clinical personnel able to order an eRx renewal. This flaw in the NextGen EHR system has allowed individuals not authorized to prescribe medications (such as RN's and LPN's) to renew an expiring prescription. This is not only dangerous, it is illegal since only licensed prescribers are authorized to order or renew a prescription. eZmar has a 'request renewal' button that the nurses can use. If this button functioned as it should, it would route the request to the prescriber; however, the system processes an automatic renewal of the prescription without the prescriber's signoff. Relator Ringold learned of this flaw while she was on vacation, when she received an email from the pharmacy asking her if she meant to change one of her patient's medication doses. Upon investigating, she learned that a nurse had ordered the renewal, thinking, mistakenly, that it would be routed to Relator Ringold for approval, but the pharmacy went ahead and processed the renewal. Relator Ringold is informed and believes that Wendy Knox, the Chief of Pharmacy for SCDC, has been discussing this flaw with NextGen and that a fix may be in process. Currently, the SCDC pharmacists have to review all eRx's to make sure an authorized provider (physician, NP, or PA) actually wrote the eRx or requested the renewal.

101. The quantity in the eRx cannot be viewed by the pharmacy. This is the case even when the prescriber clearly writes a specific quantity into the prescription. This is particularly

dangerous for 'prn' (take as needed) medications. For example, Relator Ringold has a patient with severe spinal stenosis. The patient also has a remote history of GI bleeding and can only take Motrin sparingly, so Relator Ringold only prescribes him #30/mo. She writes his prescription: "Motrin 600mg 1 po tid prn #30/mo." The language "1 po tid" means one pill orally three times per day, but since the eRx received by the pharmacy does not show "#30 mo.," the pharmacy fills the prescription with #90/mo.

102. "Reason" box empty on patient's copy of the eRx. There is a 'reason' box in prescriptions, where the prescriber can put important explanatory information, e.g., which ailment or symptom a particular medication is for. This is an important feature because patients do not always know which medication is for which ailment. In NextGen's EHR system, prescribers can provide a "reason" in the eRx, but it does not show up on the pharmacy's end to be reproduced on the patient's copy.

103. The above are representative examples of a multitude of problems with the e-prescribing functionality that render NextGen's EHR system non-compliant with Meaningful Use requirements and present a distinct risk of patient harm.

3. NextGen's EHR System Does Satisfy CPOE Requirements.

104. To be certified as a Complete EHR under the 2014 and 2015 Edition certification criteria, a vendor's software must provide computerized provider order entry ("CPOE"). CPOE requires, inter alia, that users to be able to electronically order and record medications as well as laboratory and radiology/imaging tests. This functionality must perform accurately, reliably, and safely to meet the certification requirement. NextGen's software fails to meet this functionality.

105. First, as described above, the software does not accurately, reliably, and safely

transmit medication orders.

106. Secondly, NextGen's EHR system at SCDC lacks the capacity to reliably order radiology/imaging and laboratory tests. The EHR system does not have a working interface with radiology/imaging services of any type, and has a very inadequate interface with laboratories; therefore the SCDC facilities must use the old-fashioned method of faxing orders and results.

4. NextGen's EHR Fails to Satisfy CCDA Requirements

107. "Consolidated clinical document architecture," or CCDA, is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters. Various MU criteria require an electronic summary of care document in conformance with established CCDA standards, including (i) 45 CFR § 170.314(b)(1)-(2) ("Transitions of care"); and (ii) 45 CFR § 170.314(e)(2) ("Clinical Summary").

108. In Relators' experience, NextGen's EHR has numerous flaws preventing it from meeting CCDA standards. First, Relators have never seen a clinical summary generated by NextGen's EHR system for any patients' office visit, nor have they seen the capacity to generate such a summary. Secondly, many essential aspects of the summary of care document do not even exist in the electronic record at SCDC (e.g., x-rays, lab results, outside consult reports, etc.); therefore they could not possibly be included in a CCDA document.

109. Even the information that is in the EHR is often displayed in a confusing manner. For example, NextGen's EHR displays a diagnosis list on the top of the homepage. Each time the inmate is seen by medical staff and the diagnosis is recorded, the EHR adds the diagnosis to the list again. For example, one patient, who has a mood adjustment disorder, sees his counselor monthly; on each occasion the counselor notes his diagnosis. This particular diagnosis is now

listed over 20 times in his EHR – Relator Ringold has seen charts with the same diagnosis listed 60 times -- rendering the EHR medical record largely unusable.

5. NextGen's EHR System Does Not Contain Adequate Security Protections

110. There are many bugs and glitches in NextGen's software that render it vulnerable to unauthorized changes to the medical records without required audit features. Following are a few representative examples:

a. Problems With Saving Notes of a Clinical Encounter

111. A "clinical encounter," also known as a "patient encounter," is a physical encounter in which a medical professional renders a service to the patient. Documenting the clinical encounter accurately is the cornerstone of a medical record. The integrity of the note of the clinical encounter is essential to the reliability of the EHR system.

112. NextGen's EHR does not keep a secure record of the clinical encounter because, among other problems, it does not reliably save notes in the medical record. "Saving" a note means preserving the note written by the provider intact. In NextGen's EHR system, however, after a provider writes a note, he or she often cannot reliably save the note. The problem happens randomly – sometimes the note can be saved and sometimes it cannot be saved – but when it happens, the note stays open and another individual can come in later and edit the note or even delete it altogether. This unreliability with saving the note undermines the integrity of the note.

113. Even when a note is saved, there is a flaw in the system when a second person later adds to the saved note; the system changes the author and time stamp of the original note to that of the second person.For instance, a patient at the Lieber Correctional Institute went on crisis intervention ("CI") on September 21, 2018. A male nurse entered the original CI note on

September 21 and saved the note. On September 22, 2018. a female nurse came after him and commented on the inmate's CI status. When the second nurse saved her note, this removed the prior nurse's name and left only the second nurse's name, and it changed the time stamp to the date of the second note. Thus, it appeared that the second nurse wrote the entire note herself on September 22. This was inaccurate and created the mistaken impression that the inmate was on CI status for a shorter period of time than he really was. (This is the same inmate that later committed suicide. See ¶ 92 above.) Greater preventive measures might have been put into place had the first nurse's notes been saved and the medical record accurately reflected all observations.

114. Another problem with saving notes is that even when a note is saved, there is a long delay in the note being transmitted to the provider's PAQ. (PAQ is "provider approval queue" which is essentially the provider's 'homepage' within the EHR system). Sometimes the delay can be many days (11 days in one case). This is a huge gap in the system.

b. Problems With Locking Notes of a Clinical Encounter

115. NextGen's EHR system also has a flaw concerning the "locking" of notes. "Locking" a note means permanently saving the note such that it cannot later be amended, even by the author of the note. NextGen's EHR system at SCDC does not lock notes until 30 days after the date of service, much longer than Medicare guidance and industry standards dictate.

116. Chapter 12 of the Medicare Claims Processing Manual contains the following guidance: "The service should be documented during, or as soon as practicable after it is provided in order to maintain an accurate medical record." Medicare Claims Processing Manual, Publication 100-04, Chapter 12, Section 30.6.1 A. The "as soon as practicable" standard has been interpreted by industry groups to mean that all documentation should be completed and

finalized no later than 48-72 hours after the service is provided.

117. Because notes are locked only after 30 days in NextGen's EHR at SCDC, this allows an excessively long period in which provider notes can be amended or altered. During that period, if the note is amended, it reflects the date of the last change rather than the date that the visit was actually completed. As such, encounters may be documented out of sequence and orders made during the encounters may be read in the wrong sequence, resulting in confusion and possibly incorrect treatment decisions.

6. Numerous Other Flaws In NextGen's Software Render It Noncompliant With Certification Criteria

118. The deficiencies in NextGen's EHR discussed in this complaint are representative, and are not meant to be exhaustive, of all of the flaws, defects, bugs, and problems that render NextGen's EHR noncompliant with certification criteria. The deficiencies relate to virtually all of the MU criteria, including those not mentioned above. For example:

119. Immunizations. Meaningful Use Stage 2 and Stage 3 requirements mandate provider reporting of immunizations to registries (i.e., state immunization information systems), including reporting of adult vaccination in states where such reporting is allowed. In Relators' experience, NextGen's EHR system does not reliably support this requirement.

120. Electronic Syndromic Surveillance Data. MU Stage 2 and Stage 3 require the "Capability to submit electronic syndromic surveillance data to public health agencies...." Syndromic Surveillance is "the systematic process of data collection and analysis for the purposes of detecting and characterizing outbreaks of disease in humans and animals in a timely manner." Relators have seen no evidence that NextGen's EHR has this capability.

121. CQM Measurements. Clinical Quality Measures (CQMs) are measurements that track the quality of health care services provided by Eligible Professionals. Since 2014, all

Medicare-eligible providers beyond their first year of demonstrating meaningful use are required to electronically report their CQM data to CMS using certified EHR technology in order to be able to receive an EHR incentive payment. Based on the numerous deficiencies in NextGen's EHR system experienced at SCDC, Relators are informed and believe that NextGen's EHR system does not have the ability to accurately report CQM measurements. To provide one example, the blood glucose monitoring template is unreliable. Providers are forced to keep an "insulin book" which is a big binder in which each inmate has a page where each blood sugar reading is recorded.

122. Drug-Drug and Drug Allergy Checks. To be certified as a Complete EHR, an EHR must reliably perform drug-drug and drug-allergy checks in an accurate and safe manner. Based on their experience with NextGen's EHR system, Relators are informed and believe that NextGen's software does not satisfy this requirement. Among other problems, the EHR system checks for drug interactions with discontinued medications, generating a number of false alerts.

123. Inability to Generate Important Reports. NextGen's EHR system is unable to generate many reports that are essential for care management of a large patient population. For example, as noted above, the system is unable to generate an expiring medication report. See ¶ 90 above. Likewise, the EHR system is not able to generate a usable report for all staff encounters during the day, or a report of all patients with a particular diagnosis. This lack of functionality greatly undermines the utility of the EHR system.

124. Additional failings. The failings of NextGen's EHR system and eZmar discussed in this complaint are representative, and are not meant to be exhaustive, of all of the flaws, defects, bugs, and problems that render the EHR system noncompliant with certification criteria. Accordingly, Relators allege on information and belief that NextGen's software is unable to meet

the majority of federal Meaningful Use standards, implementation specifications, and certification criteria not specifically mentioned above, including but not limited to data portability requirements, interoperability requirements, and vocabulary standards (etc. RxNorm, Snomed, LOINC).

125. Because of all of the deficiencies in Defendants' software, their EHR products lack the most fundamental requirement of any EHR system: usability on a practical level. As such, not only do Defendants' EHR products not meet meaningful use standards, but they also do not meet the basic requirements for direct purchase by public entities or continued certification by the accreditation and testing agencies.

D. Conduct Implicating the Anti-Kickback Statute

126. Relators are informed and believe that NextGen paid remuneration to individuals to induce them to recommend the adoption of NextGen's EHR in the SCDC prison system. Relators are further informed and believes that NextGen engages in similar conduct to promote its product in the private sector.

127. Paying remuneration to influence the adoption of a system that generates claims on the United States violates the AKS.

128. Requests to the Federal Government for incentive payments that resulted from unlawful kickbacks constitute false claims.

VI. CLAIMS FOR RELIEF

129. Based on the extreme lack of reliability and functioning of Defendants' EHR software in South Carolina's prisons, Relators are informed and believe that the problems described herein are representative of fundamental flaws in the software in every setting in which it is used.

130. Based on their experience with the functional failings of Defendants' EHR systems, Relators allege that Defendants obtained EHR certification for the NextGen EHR through a series of false statements and fraudulent conduct. The NextGen EHR system did not—and could not—meet both the certification criteria and the requirements for direct purchases and/or incentive payments from federal, state and local governments. Those failures persist to this day.

131. Defendants attempted to conceal the failure from federal, state and local governments. Defendants caused Eligible Professionals falsely to attest to using certified EHR technology to satisfy Meaningful Use objectives and measures and caused Eligible Professionals to submit false information on their attestations requesting incentive payments.

132. In addition, Defendants fraudulently induced public entities to purchase Defendants' EHR products by concealing the flaws discussed in this Complaint

133. Through the conduct discussed above, Defendants knowingly caused the submission of false claims and false statements material to false claims to be submitted to the Government.

134. Every claim for payment knowingly submitted or caused to be submitted to the Government for payments for use of Defendants' software, whether through direct purchase or incentive payment programs, that does not meet procurement and/or Meaningful Use requirements is a false or fraudulent claim in violation of the FCA.

135. In addition, NextGen's violations of the Anti-Kickback statute caused providers to submit false claims for payment to the Government.

Count One
False Claims Act
U.S.C. §§ 3729(a)(1)(A), (B), (C), & (G)

136. Relators reallege and incorporate by reference the allegations contained in paragraphs 1 through 135 above as though fully set forth herein.

137. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, et seq., as amended.

138. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

139. By virtue of the acts described above, Defendants knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims for payment by the Government.

140. By virtue of the acts described above, Defendants knowingly caused its customers to conceal or improperly avoid or decrease an obligation to pay or transmit money or property to the Government;

141. By virtue of the acts described above, Defendants knowingly conspired to violate the FCA. Moreover, Defendant took substantial steps toward the completion of the goals of that conspiracy by the conduct alleged herein.

142. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by several separate entities. Relator does not have access to the records of all such false or fraudulent statements, records or claims.

143. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

144. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

145. Additionally, the United States is entitled to the maximum penalty for each and every violation arising from Defendants' unlawful conduct alleged herein.

PRAYER

WHEREFORE, *qui tam* Plaintiff-Relators Toby Markowitz and Elizabeth Ringold pray for judgment against the Defendants as follows:

1. That Defendants cease and desist from violating 31 U.S.C. § 3729 *et seq*.

2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty for each violation of 31 U.S.C. § 3729;

3. That Relators be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act.

4. That Relators be awarded all costs of this action, including attorneys' fees and expenses; and

5. That Relators recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relators hereby demand a trial by jury.

Dated: November 14, 2018

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